K011860

JUN 2 7 2001

510(K) SUMMARY

This summary of 5l0(k) -safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____

1. Submitter's Identification:

Tony Madison, President
Keystone Medical
1338 Michael Way
Lansdale, PA. 19446

Date Summary Prepared: May 29, 2001

2. Name of the Device:

Keystone Medical Peripherally Inserted Central Catheter (PICC)

3. Predicate Device Information:

These devices are substantially equivalent to devices currently marketed by Medical Components, Inc, Lansdale, PA under K#953811. Medical Components will continue to manufacture these devices.

4. Device Description:

Single or double lumen intravenous catheters. Devices will be assembled in a kit that includes components that are either legally marketed; exempt from premarket requirements; or "grandfathered".

5. Intended Use:

The devices are intended for use when central venous catheterization or intravenous therapy for the administration of fluids, medications and/or nutritional therapy is prescribed. The use of the device for these indications is less than 30 days.

6. Comparison to Predicate Devices:

The Keystone Medical Lumen Catheter is identical to the predicate.

The Keystone device will differ only in that the Keystone Medical name and logo will appear on the unit labels, box labels, and instructions for use. Keystone will also develop it's own sell sheets for these devices in the future.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Non clinical (bench) testing was completed to support K#953811, and was included with this 510(k) submission

8. Discussion of Clinical Tests Performed:

Clinical testing was not completed.

9. Conclusion

The Keystone Medical PICC catheters are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2001

Keystone Medical
C/O Mr. Alan P. Schwartz
Executive Vice President
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K011860
Trade/Device Name: Keystone Medical PICC Catheter
Regulation Number: 880.5200
Regulatory Class: II
Product Code: FOZ
Dated: June 12, 2001
Received: June 14, 2001

Dear Mr. Schwartz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Keystone Medical
PICC Catheter
Indications for Use

Attachment 3

510(k) Number: K011860

Device Name: Keystone Medical PICC Catheters

Indications for Use:

The devices are intended for use when central venous catheterization or intravenous therapy for the administration of fluids, medications and/or nutritional therapy is prescribed. The use of the device for these indications is less than 30 days.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **(Per 21 CFR 801.109)** OR **Over-The-Counter Use** ____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011860

(Optional Format 1-2-96)